

EXHIBIT 3

1 IN THE UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF WEST VIRGINIA
3 AT CHARLESTON

4 -----X
5 IN RE: ETHICON, INC., PELVIC Master File No.
6 REPAIR SYSTEM PRODUCTS 2:12-MD-02327
7 LIABILITY LITIGATION MDL 2327

8 -----X
9 THIS DOCUMENT RELATES TO THE JOSEPH R. GOODWIN
10 FOLLOWING CASES IN WAVE 1 OF U.S. DISTRICT JUDGE
11 MDL 200:
12 Dorothy Baugher v. Ethicon, Inc., et al.
13 Civil Action No. 2:12-cv-01053

14 Denise Sacchetti v. Ethicon, Inc., et al.
15 Civil Action No. 2:12-cv-01148
16 Sheri Scholl, et al. v. Ethicon, Inc.
17 Civil Action No. 2:12-cv-00738

18 Lisa Thompson, et al. v. Ethicon, Inc., et al.
19 Civil Action No. 2:12-cv-01199
20 Roberta Warmack, et al. v. Ethicon, Inc., et al
21 Civil Action No. 2:12-cv-1150

22 Rebecca Wheeler, et al. v Ethicon, Inc., et al.
23 Civil Action No. 2:12-cv-01088
24 Thelma Wright v. Ethicon, Inc., et al.
25 Civil Action No. 2:12-cv-01090

26 -----X
27 VIDEOTAPED DEPOSITION OF
28 S. ABBAS SHOBEIRI, M.D.

29
30 Fairfax, Virginia
31 February 27, 2016
32 Reported by: Denise D. Vickery, CRR/RMR

1

2

3 February 27, 2016

4 10:06 a.m.

5

6

7 VIDEOTAPED DEPOSITION OF S. ABBAS SHOBEIRI, MD,
8 held at Gathering Room 3 of:

9

10

11 HYATT HOUSE MERRIFIELD

12 8296 Glass Aly

13 Fairfax, VA 22031

14

15

16

17 Pursuant to notice, before Denise D. Vickery,
18 Registered Merit Reporter, Certified Realtime
19 Reporter, and Notary Public in and for the
20 Commonwealth of Virginia.

21

22

23

24

1 in fact, are defective?

2 A. You mean do I have an opinion about
3 it?

4 Q. Yes. Do you have an opinion about
5 it?

6 A. They have their own set of problems.

7 Q. I'm not sure that was an answer to
8 my question, Doctor.

9 A. Uh-huh.

10 Q. Do you have an opinion that they are
11 defective?

12 A. Could you define "defective"?

13 Q. Any way you want to use it. In your
14 own terminology.

15 A. So would I be using transobturator
16 tapes? Is that what you're asking or --

17 Q. Sure. Go ahead if you want to
18 answer it that way.

19 A. I think that generally we try to
20 restrict ourselves to the retropubic TVT type
21 products.

22 Q. Okay. So in your practice, you
23 don't use any transobturator products, whether
24 it's inside-out or outside-in.

1 Fair statement?

2 A. Well, I used to use TVT-O, but
3 patients had problems and I stopped it. And I
4 used to use the transobturator tapes, and
5 patients had problems and I stopped it.

6 Q. So the answer to my question is:
7 You do not use any transobturator product now?

8 A. No, because the patients have
9 problems.

10 Q. Okay. Doctor, I appreciate and I'm
11 not trying to limit your answers, but if you
12 would answer my question, this would go quicker.

13 A. Uh-huh.

14 Q. Fair enough?

15 A. Fair.

16 Q. Okay. When did you stop using
17 transobturator products, whether of the
18 inside-out surgical technique or outside-in
19 technique?

20 A. The -- we used the transobturator
21 tapes -- I used the transobturator tapes when
22 they initially came out, and for me they had, you
23 know, issue with mesh erosion, which I didn't
24 like. So we went to -- I went to TVT-O and that

1 had its own complications, and we didn't like it.

2 So in terms of when we stopped it, I
3 probably stopped using TOTs -- I'm just going by
4 memory -- probably about five -- five years ago
5 or so, and I may have used TVT-O for about three
6 years or so before I stopped that.

7 Q. When did the transobturator products
8 come on the market; do you remember?

9 MS. THOMPSON: Object to form.

10 THE WITNESS: Hmm. Well, they
11 have been on the market probably as early
12 as 2000s, somewhere about that.

13 BY MR. OTTAWAY:

14 Q. And as I understood your testimony,
15 you said you stopped using them in 2011 or so?

16 A. Well, I switched to the TVT-O at
17 that point.

18 Q. Okay.

19 A. Yeah.

20 Q. And how long did you use TVT-O after
21 2011 before you stopped using it?

22 A. Hmm. Probably about a few years,
23 three, four years.

24 Q. So maybe 2013 or '14?

1 A. No, no. We -- I think I -- so it
2 was sequential where we were -- where -- where I
3 was using TOTs probably up to 2010 or so and then
4 switched to TVT-O for a few years.

5 Q. Again, so if you stopped using the
6 others and started using TVT-O by Ethicon in 2010
7 and used it for a couple of years, would your
8 testimony and best recollection be that you used
9 the TVT-O product up until about 2012 or '13?

10 A. That's probably true.

11 Q. All right.

12 A. Let me see. It's 2016 now. Yeah.

13 Q. Fair?

14 A. Fair.

15 Q. Okay. And during the period of time
16 you used transobturator products in general --

17 A. Uh-huh.

18 Q. -- how many implants did you
19 perform?

20 A. So we are talking about the TVT-O?

21 Q. Any of the transobturator products,
22 and then I'll narrow it to TVT-O.

23 MS. THOMPSON: And the
24 transobturator products? Slings?

1 MR. OTTAWAY: Yes.

2 MS. THOMPSON: Okay.

3 MR. OTTAWAY: Yes, and I think
4 the doctor knows that's what I'm referring
5 to. I asked him at the beginning of the
6 deposition to limit his testimony to the
7 TVT-O sling.

8 THE WITNESS: Well, actually, I
9 was thinking about the same thing.

10 BY MR. OTTAWAY:

11 Q. Good. Okay.

12 A. So, yeah, we still use the trans- --
13 I use the transobturator tapes infrequently.
14 Mainly use it in patients that I felt like they
15 may have had retropubic scarring or prior
16 surgeries where using the TVT would increase
17 their risk of bladder injury.

18 So I cannot give you a number in
19 terms of. I would say the transobturator tapes
20 are probably more than 50. Is that fair?

21 Q. I'm having to rely on you, Doctor,
22 and your memory.

23 So somewhere around 50 you think?

24 A. 50? It's probably fair to say more

1 than 50.

2 Q. More than 50. Okay.

3 And of the 50, how many were TVT-O?

4 A. Well, these were just probably TOTs.

5 So then -- then I switched to TVT-O.

6 Q. Okay. And how many TVT-O procedures
7 did you perform?

8 A. Probably more than 30.

9 Q. So roughly 50 and roughly 30, about
10 80 total?

11 A. I'm guessing. Could be more.

12 Q. Give me the parameters, Doctor. I
13 just -- I'm not trying to hold you to specific
14 number.

15 A. Uh-huh.

16 Q. I just want to know roughly your
17 best guess.

18 A. Hmm. I think it's fair to say I
19 have performed -- I performed more than 50 TOTs,
20 and it's fair to say that I performed more than
21 30, upwards of 50 TVT-Os.

22 Q. Okay. So that would take you
23 somewhere up around a hundred total?

24 A. It's a good guess.

1 Q. All right. Now, you stopped using
2 the TVT-O in 2012 or '13, roughly.

3 A. Uh-huh.

4 Q. Did the product remain on the market
5 and available to surgeons after you stopped using
6 it?

7 A. I believe so.

8 Q. In 2012 or 2013, as I recall your
9 résumé, you were at the -- in Oklahoma at an
10 institution, were you not?

11 A. True.

12 Q. What institution was that?

13 A. At the University of Oklahoma.

14 Q. And at the University of Oklahoma,
15 were there other physicians in your profession
16 and specialty that continued using TVT-O after
17 you stopped using it?

18 A. Hmm. Actually, my partners at the
19 university had reservations using TVT-O. So they
20 never actually used TVT-O, and they are not using
21 TVT right now.

22 Q. Okay. So it's your testimony that
23 your partners at OU are not using TVT-O?

24 A. They may have picked it up since

1 Washington, DC area?

2 A. Northern Virginia.

3 Q. Okay.

4 A. I'm at the Inova Health Care.

5 Q. Okay. Tell me about Inova. What is

6 Inova and your job with Inova?

7 A. Inova is a mile down the road from
8 here. When you drive down, you can see one of
9 their hospitals. It's a hospital system with
10 five, six hospitals serving Northern Virginia.
11 It's the Northern Virginia campus for Virginia
12 Commonwealth University.

13 So I'm a professor of OB-GYN for
14 Virginia Commonwealth University. I'm a
15 professor of OB-GYN at George Washington
16 University. I'm a professor of OB-GYN at OU
17 still, and I'm a professor of cellular biology
18 and anatomy at OU still.

19 Q. And does the Inova Hospital chain
20 that you've described have physicians in your
21 specialty who use TVT-O?

22 A. No.

23 Q. Okay. Does the University of
24 Virginia Commonwealth have a hospital associated

1 that has been approved or vetted by the FDA?

2 A. No.

3 Q. Are you an expert in FDA regulatory
4 matters?

5 A. I know a lot about FDA regulatory
6 matters.

7 Q. My question was: Do you consider
8 yourself an expert in FDA regulatory issues?

9 A. Could you define "expert"?

10 Q. You -- you're the one that mentioned
11 it. I'm just asking you if you consider yourself
12 to be an expert in FDA regulatory matters.

13 A. I know more than a lot of other
14 people.

15 Q. Okay. Have you worked -- been hired
16 by the FDA to work on regulatory issues?

17 A. No.

18 Q. Have you ever worked with a device
19 manufacturer to gain FDA approval for a medical
20 device?

21 A. Yes.

22 Q. Okay. Tell me about that.

23 A. I'm not sure if I can because we
24 signed confidentiality agreement.

1 Q. Well, obviously I don't want you to
2 violate a confidentiality agreement.

3 A. Uh-huh.

4 Q. But you're going to have to give me
5 some idea for whom, when, what in general was
6 involved.

7 A. Hmm. AMS.

8 Q. Okay. Tell me about what you did
9 for AMS in general.

10 MS. THOMPSON: Only to the extent
11 that you can under your agreement.

12 THE WITNESS: Well, we trialed
13 the -- we trialed TOPAS.

14 BY MR. OTTAWAY:

15 Q. TRIaled? I'm sorry. TRIaled TOPAS?

16 A. Uh-huh. T-O-P-A -- is it S or Z? I
17 don't know. I think that's it.

18 Q. Okay. And what is TOPAS?

19 A. It's a fecal incontinence product.

20 Q. And does it involve any kind of
21 synthetic mesh?

22 A. Yes.

23 Q. Okay. What kind of mesh product is
24 used in TOPAS that you were involved with?

1 A. Well, we -- it was their -- their
2 version of polypropylene.

3 Q. And how is it -- how does it differ
4 from a polypropylene used in TVT-O if you know?

5 A. It's just the way it's woven is
6 probably different.

7 Q. Okay. And tell me how the way it is
8 woven is different than TVT.

9 A. So, for example, TVT-O when you
10 implant it and it frays and the little pieces of
11 mesh come undone, you can actually see it on your
12 hand. That is, when you pull the sheet out, the
13 sling rolls into sort of tubular structure and,
14 you know, just as it gets stretched, the -- the
15 holes in the mesh are not as the size that they
16 were designed. So -- so it's just different.

17 Q. Okay. And, again, how is it
18 different? I'm -- I'm -- is it --

19 A. So the TVT-O when you insert it,
20 when you take the plastic sheet out, you know, it
21 frays. The little piece of mesh can come on your
22 hand and then it can also roll, and also it
23 stretches where the holes that are there sort of
24 become smaller.

1 Q. Right. You told me that, but I want
2 to know how the polypropylene used in TOPAS
3 differs from the polypropylene used in TTVT-O.

4 A. It's just different design.

5 Q. Okay. And how is the design
6 different?

7 A. The -- the weave is different.

8 Q. Okay. Weave.

9 A. Uh-huh.

10 Q. Anything else?

11 A. I think that's mostly what
12 differentiates them, and also the -- just the way
13 it designed. It's not -- doesn't stretch like
14 TTVT-O.

15 Q. Okay. So its application is
16 different?

17 A. No. It's just woven differently, so
18 it wouldn't be as stretchy.

19 Q. Does it differ -- differ in chemical
20 property?

21 MS. THOMPSON: Object to form.

22 THE WITNESS: The chemical
23 property. The polypropylene? When you say
24 "chemical property," like is it like made

1 differently or --

2 BY MR. OTTAWAY:

3 Q. Yes.

4 A. -- what do you mean?

5 So, no, it's polypropylene and it's
6 just woven differently.

7 Q. All right. Is TOPAS on the market?

8 A. It -- well, it has gone through its
9 FDA trial, and I believe it just got a hearing
0 recently.

11 Q. Okay. What exactly was your role in
12 the trial for TOPAS mesh?

13 A. I studied the anatomical course of
14 the sling, both in cadavers and in live patients,
15 with ultrasound, and we did the trials.

16 Q. Okay. Were you involved in
17 preparing any written materials that were to
18 accompany or are to accompany TOPAS if it's
19 released to the market?

20 A. Could you repeat that question?

21 MR. OTTAWAY: Can you read that
22 back to him again? I'm not sure I can ask
23 it any better.

24 (The reporter read the record on

1 urinary incontinence can and does adversely
2 affect the quality of life for women?

3 A. I agree with you.

4 Q. Do you agree with me that
5 mid-urethral slings are the standard of care for
6 the treatment of stress urinary incontinence?

7 MS. THOMPSON: Object to form.

8 THE WITNESS: The surgical
9 standard of care, yeah.

10 BY MR. OTTAWAY:

11 Q. Okay. Is that position shared by
12 the organizations we just mentioned of which you
13 are a member, AUGS and ACOG?

14 A. I think those are the standard of
15 care, yeah.

16 Q. And would you agree with me that
17 TVT-O is a type of mid-urethral sling?

18 A. That's debatable whether it ends up
19 in mid-urethral or not.

20 Q. Do you believe it's a mid-urethral
21 sling or not?

22 A. I believe it's not placed
23 mid-urethral.

24 Q. Okay. Have either AUGS or ACOG

1 taken a position that TVT-O is not a mid-urethral
2 sling?

3 A. Let me correct myself.

4 In the TVT-O IFU, where they say to
5 make the incision does not facilitate putting the
6 sling in mid-urethral. ACOG and AUGS support
7 mid-urethral slings.

8 Q. Have ACOG or AUGS taken a position,
9 to your knowledge, indicating that TVT-O is not
10 within the category of mid-urethral slings?

11 A. I believe they have not delineated
12 that.

13 Q. All right. We've been going about
14 45 minutes, Doctor. Let's take a break.

15 And anytime you need to take a
16 break, by the way, if you'll just answer the
17 question on the table and tell me you need to
18 take a break, we'll do it at your convenience as
19 well.

20 Fair enough?

21 A. That's great.

22 MR. OTTAWAY: Okay.

23 THE VIDEOGRAPHER: Time now is
24 10:49. We are going off the record.

1 THE VIDEOGRAPHER: Time now is
2 12:03. We are back on the record. This is
3 the beginning of disk No. 2.

4 BY MR. OTTAWAY:

5 Q. Dr. Shobeiri, I had referred you
6 when we broke to page 5 of your report, which is
7 titled "Summary of Opinions."

8 A. Yes, sir.

9 Q. Have you had a chance to review that
10 while we were on break?

11 A. No. I was actually looking at IFU.

12 Q. Okay. Well, I take it you're
13 familiar with these opinions?

14 A. Yes.

15 Q. And I want to ask you about them --

16 A. Uh-huh.

17 0. -- one at a time.

18 A. Sure.

19 Q. Tell me about opinion number 1.

20 What is your opinion and upon what do you base
21 it?

22 A. Mesh complications are unlike those
23 seen with the other pelvic surgery in terms of
24 onset, frequency, severity, character.

1 responsiveness to treatment.

2 So in terms of TVT-O, the mesh arms
3 are going through a space that generally
4 obstetrician/gynecologists were not familiar
5 with. So the kind of problems that occurred in
6 terms of dealing with those problems, really
7 understanding the frequency, the severity, the
8 character of them, how to respond to, are very
9 difficult.

10 Q. Okay. And --

11 A. So traditional pelvic surgery,
12 complications that OB-GYNs were used to were, you
13 know, urethral injury or bladder injury or those
14 kind of things. So these are very unique type of
15 problems.

16 Q. Okay. Tell me exactly what you
17 refer to when you say "complications."

18 MS. THOMPSON: Object to form.

19 THE WITNESS: Complications in
20 terms of TVT-O, we are talking about the
21 spaces traversing the response of local
22 tissue to mesh in that area, the proximity
23 of the sling arm to nerve vasculature that,
24 you know, were just unfamiliar territory.

1 BY MR. OTTAWAY:

2 Q. I'm really trying to understand,
3 Doctor, but you've kind of skipped down to what I
4 think would be number 6 or 7 or one of the
5 others.

6 Does this refer to TVT-O
7 specifically or mesh products in general?

8 A. I think in terms --

9 Q. Number 1.

10 A. Yeah. In terms of this report, we
11 are talking about TVT-O.

12 Q. Okay. And when you say "mesh" up
13 here in number 1, you mean TTVT-O?

14 A. I think we are talking -- saying
15 TTVT-O mesh complications.

16 Q. Okay. Thank you for that.

17 And why do you say they differ in
18 severity, frequency, and responsiveness to
19 treatment? I want to know the basis of those
20 opinions.

21 A. Uh-huh. So because the mesh arms --
22 and all of these opinions really melt into each
23 other -- go through a space that OB-GYNs were not
24 traditionally familiar with.

1 Q. Are you talking about the --

2 A. Obturator space.

3 Q. -- obturator space?

4 A. Yeah.

5 Q. Okay.

6 A. So in terms of frequency, they
7 didn't know how frequently that would occur. If
8 it occurred, in terms of severity, they didn't
9 know how severe it could be, what character to
10 expect, and how to respond to it.

11 Q. Okay. And in your mind, is there a
12 difference between the inside-out and outside-in
13 technique for purposes of your criticism
14 number 1?

15 A. Well, the TVT-O course is -- can be
16 unreliable and -- and they do travel tracts that
17 are different.

18 Q. Okay. Tell me how that is.
19 Describe to me the different tracts, if you will,
20 and why that makes a difference, if it does, to
21 your opinion.

22 A. Uh-huh. So, for example, I told you
23 with the TOTs at one point and the problem with
24 that was that, you know, you -- you had the

1 ability to hug the bone as you were coming
2 around, but then the problem it posed was that it
3 would be too close either to the vaginal skin or
4 perforate the skin. So you have erosion problem,
5 and that was the problem that was recognized.

6 And potentially TVT-O going from
7 inside-out would alleviate that problem, but then
8 the trajectory of the needle going the other way
9 into the thigh to the mesh to a separate area.

10 Q. Okay. And what did that have to do
11 with the onset frequency, severity, character of
12 the injury, or responsiveness to treatment?

13 A. Well, you are putting the mesh close
14 to the anterior and posterior branches of the
15 obturator nerve. So you're -- you're operating
16 in a space that people are not used to, and
17 you're not really foreseeing that those nerves
18 are there and what the body response would be to
19 it in terms of pain. So that creates unique
20 problems.

21 Q. Okay. And what -- how do those
22 problems manifest?

23 A. Leg pain, groin pain, you know, and
24 the company thought that they would go away

1 within the first 24 hours, 48 hours but, you
2 know, when they persist, they don't go away even
3 if after you try to remove the mesh.

4 Q. Okay. Have you reviewed
5 peer-reviewed literature which suggests that this
6 leg and groin pain is transitory?

7 MS. THOMPSON: Object to form.

8 BY MR. OTTAWAY:

9 Q. You can answer, Doctor.

10 A. Have I reviewed? So the -- yeah,
11 there is the data in the literature that as high
12 as like 25 percent of patients can have this pain
13 to begin with, and it sort of settles down to
14 somewhere about 3 percent that is persistent.

15 Q. Okay. Your second opinion -- have
16 you finished on number 1?

17 A. Sure.

18 Q. Okay. Number 2. Three-dimensional
19 endovaginal ultrasound is a reliable,
20 reproducible, etc.

21 Tell me what your opinion is there
22 and how it relates to TVT-O.

23 A. Sure. So pelvic floor ultrasound
24 has been used for many, many years and used to

1 have what --

2 A. Does it have --

3 Q. -- counsel provided me.

4 A. Does it on top say updated what
5 date?

6 Q. I can answer that question, but it's
7 at the bottom.

8 A. I'm sorry.

9 Q. And it says it was updated
10 February 1, 2016 at 8:01 a.m.

11 A. So that means it's pretty recent.

12 Q. Okay. So my question, again, is:
13 There are three articles or three works here that
14 are attributed to you and Mr. Javadian?

15 A. Javadian, yeah.

16 Q. Javadian. I want to pronounce it
17 correctly.

18 The first being "Ultrasonic
19 Predictors of Mesh Complications." It says "In
20 progress."

21 A. Okay.

22 Q. The next one is "Transobturator Tape
23 Syndrome: Ultrasonic Predictors of Pain." It
24 says "in progress."

1 A. In progress.

2 Q. And the third is "Public Health

3 Impact of Vaginal Mesh Complications on Women's

4 Health: In progress."

5 A. I know that one has been submitted.

6 Q. Okay. Submitted to whom?

7 A. Probably American Journal of OB-GYN.

8 Q. Okay. And has it been accepted for
9 publication?

10 A. I'm not sure.

11 Q. So it exists in some form we can see
12 that's been submitted to a journal?

13 MS. THOMPSON: Object to form.

14 And you can answer the question
15 but -- but --

16 THE WITNESS: The one --

17 MS. THOMPSON: -- but subject to
18 whatever the standard is for submitted
19 publications that have not yet been
20 published.

21 THE WITNESS: Yeah. We can -- we
22 can give you the Public Health impact paper
23 probably. I will check with my counsel and
24 see how that goes.

1 and 10.

2 THE WITNESS: So there are a lot
3 of articles supporting this. I have to see
4 the actual articles to put it out for you.

5 BY MR. OTTAWAY:

6 Q. Okay. So you're not able to tell me
7 just looking at the --

8 A. Yeah. They --

9 Q. -- exhibit I handed you?

10 A. They are a lot of articles and there
11 are a lot of them that each of them looks at a
12 different point, and I'll be happy to give you
13 that information if I have the actual papers.

14 Q. Okay. Just keep going there,
15 Doctor, and I want to take all the other opinions
16 and ask you the same kind of thing.

17 Do you have any particular support
18 you're relying on for them, or is this just,
19 again, contained somewhere in your reliance
20 materials?

21 A. For the what question?

22 Q. The rest of them, 10 on.

23 A. Yeah, I think they're all in the
24 references that we have given you.

1 all of them do that?

2 BY MR. OTTAWAY:

3 Q. Yes.

4 A. No. I mean, we have seen slings
5 that don't do that.

6 Q. Okay. Tell me who manufactured
7 those slings.

8 A. Who manufactures the slings that
9 don't roll?

10 Q. Yes.

11 A. Well, for example, the -- most of
12 the TVT type slings that we look at, they don't
13 roll. They sit straight.

14 Q. Well, no. My question was
15 specifically limited to transobturator slings.

16 A. Well, the TVT-Os we have looked at,
17 they roll and they cause problems. And I told
18 you we don't use TOTs anymore.

19 Q. Okay. Well, have you done a study,
20 though, of TOTs in the same way that you have
21 looked at TVT-Os to determine whether they roll,
22 fray, curl?

23 A. Uh-huh.

24 Q. Tell me what you found.

1 A. Well, the -- I think that both TOTs
2 and TVT-Os can behave the same to some degree.
3 The -- the ones that I have looked at have been
4 the TVT-O and the Bard product, and I know those
5 ones roll and cause issues.

6 Q. Okay. Any others that you've looked
7 at?

8 A. There are some others, but off the
9 top of my head, I would say that we have looked
10 at some Boston Scientific products that also do
11 the same thing. Their transobturators. So those
12 are the three I can think of.

13 Q. So TVT-O is not unique in that
14 regard?

15 MS. THOMPSON: Object to form.

16 THE WITNESS: The TVT-O probably
17 is not unique in that regard, and but we
18 are not using TOTs or TVT-Os.

19 BY MR. OTTAWAY:

20 Q. Doctor, if you can go to page 26 of
21 your report. Middle paragraph starts "There
22 are." Are you with me?

23 A. Sure.

24 Q. Okay. Tell me what in your opinion

1 would have provided a safer alternative.

2 A. Well, in our practice, we are
3 basically using the retropubic devices. We're
4 using the TVT type devices.

5 Q. TVT devices manufactured by Ethicon?

6 A. Ethicon, Boston Scientific. You
7 know, depends on what the hospital is providing
8 us.

9 Q. So when you say "safer alternative,"
10 you mean retropubic TVT devices?

11 A. Yeah, that's the --

12 MS. THOMPSON: Object to form.

13 THE WITNESS: Those are the safer
14 things.

15 MR. OTTAWAY: You have to let her
16 get her objection out, Doctor.

17 Do you have an objection,
18 counsel?

19 MS. THOMPSON: Object. Yeah, I
20 object to form.

21 MR. OTTAWAY: Thank you.

22 BY MR. OTTAWAY:

23 Q. You may answer, Doctor. I'm sorry.
24 If you can remember the question?

1 A. Yeah. So we have -- we have moved
2 to the more retropubic slings.

3 Q. Okay.

4 A. And we don't have TVT-Os on the
5 shelf.

6 Q. Okay. And those include TVT devices
7 made by Ethicon?

8 A. TVT devices by -- made by Ethicon.

9 Q. Okay. And when you say "safer
10 alternative," that's what you mean?

11 MS. THOMPSON: Object to form.

12 THE WITNESS: That's what we are
13 using now.

14 BY MR. OTTAWAY:

15 Q. Okay. Well, no. I'm asking you if
16 that is the safer alternative you're referencing
17 at page 26 of your report?

18 A. Yes. We are avoiding transobturator
19 space and going to retropubic in appropriate
20 patients.

21 Q. Okay. Is there medical literature,
22 Doctor, of what you're aware in peer-reviewed
23 journals which suggests that TVT devices and
24 TVT-O devices are equivalent --

1 MS. THOMPSON: Object to form.

2 BY MR. OTTAWAY:

3 Q. -- when it comes to safety and
4 efficacy?

5 A. I'm aware of literature that say
6 they are not equivalent.

7 Q. That wasn't my question again,
8 Doctor.

9 If you can answer my question. I
10 appreciate your answer, but can you answer my
11 question?

12 A. Yes, there is literature saying that
13 depending on the end point that they were looking
14 at, those end points are equivalent.

15 Q. Okay. Thank you.

16 I noticed here at the last page of
17 your report that you've already told us that
18 you've stopped using TVT-O; correct?

19 A. Uh-huh. True.

20 Q. Are you aware of any academic center
21 currently using TVT-O?

22 A. No, but that doesn't mean somebody
23 out there is not using it.

24 Q. Have you made any effort to search

1 and find out that information?

2 A. The people I have talked to and the
3 people who are within my communication space are
4 not using it, but it doesn't mean somebody out
5 there is not.

6 Q. Okay. Even in an academic center?

7 A. True.

8 MR. OTTAWAY: How are we doing on
9 time, Mr. Videographer?

10 THE VIDEOGRAPHER: Nine minutes
11 to go.

12 MR. OTTAWAY: All right. Good.
13 We'll finish out the nine minutes then.

14 BY MR. OTTAWAY:

15 Q. You have reviewed the IFU for TVT-O,
16 Doctor?

17 A. Yes, I did.

18 Q. When you were performing TVT-O
19 surgeries, had you reviewed it prior to doing
20 them?

21 A. Yes.

22 Q. Did you also conduct your own review
23 of literature to determine how other people were
24 doing with the TVT-O or TOT device?

1 A. I believe when we started using
2 either of them, you know, we reviewed the
3 available literature and we read the IFU.

4 Q. And that's why you say you practice
5 evidence-based medicine; correct? Because that's
6 something you do, review the literature before
7 you start using a product?

8 MS. THOMPSON: Object to form.

9 THE WITNESS: We review the
10 literature and read the IFU before we use
11 the product.

12 BY MR. OTTAWAY:

13 Q. But you don't do one to the
14 exclusion of the other; correct?

15 A. True.

16 Q. And you would expect other doctors
17 sharing your specialty to do the same. True?

18 MS. THOMPSON: Object to form.

19 THE WITNESS: True.

20 BY MR. OTTAWAY:

21 Q. Now, you talk about adverse
22 reactions that are listed in the IFU.

23 A. What page?

24 Q. I'm not trying to fool you here,

1 were on page 25. If you'll flip over to page 26,
2 first paragraph, and then we'll come back to 25
3 because I wanted to get at this.

4 A. Sure.

5 Q. You reference in that paragraph:

6 "Information known to Ethicon from
7 internal documents."

8 Do you see that?

10 Q. Page 26.

11 A. (Reading document).

12 Q. Fourth sentence.

13 A. Oh, we're talking about the

14 reference 26 or --

15 Q. Yes. Yes.

16 A. Okay. So what's the question?

17 Q. Okay. I want to know if this

18 information known to Ethicon from internal
19 documents is contained within the same documents
20 that we showed you before in Exhibit 2 or if
21 you're referring to something else there.

22 A. Cannot find the sentence you're
23 talking. Let me just see.

24 O. Starts with "These" in sentence or

1 line 3.

2 A. Page 26; right?

3 Q. Page 26, line 3. Starting -- the
4 sentence starting "These." You'll notice
5 something --

6 A. "These statements are misleading and
7 inaccurate"; right? "Based on the information."

8 Q. Right. That's what I'm asking.

9 "Information known to Ethicon from
10 internal documents."

11 Do you see that?

12 A. Yes.

13 Q. And are those internal documents the
14 same ones we referred to earlier, or are you
15 referring to other documents?

16 A. No, we are -- I'm -- I'm referring
17 to the documents that we have here in one of the
18 exhibits.

19 Q. Exhibit 2, I believe.

20 A. Exhibit 2 and also the references
21 26.

22 Q. Right. To the literature.

23 A. Yes.

24 Q. The only internal documents you're

1 I asked you: Do you hold yourself
2 out as an expert in biomaterials?

3 A. I'm not a biomaterial engineer.

4 Q. All right. Doctor, I'd like to ask
5 you a question. If you want to refer to page 27,
6 but it's referred to in several pages in your
7 report.

10 A. A community doctor? Where do I --
11 ah, I see here.

Community doctors are physicians who
are working in the community. Probably
physicians in nonacademic centers.

15 Q. And would they be gynecologists,
16 urogynecologists?

17 A. Or -- or physicians in a non- --
18 non-tertiary type health centers.

19 Q. Would they be doctors who had access
20 to the same reference material that you refer to
21 in your Exhibit B to your report?

22 A. They would have access to it, but
23 remember, for me I'm always reading articles
24 continuously where those physicians may have

1 certain societies they belong to or they would --
2 they may read one or the other journal.

3 Q. They can be doctors who are
4 specializing in your specialty? Members of the
5 same societies you're members of?

6 A. So are there community physicians
7 who are urogynecologists? There are community
8 urogynecologists as well.

9 Q. Now, the reason I ask that is
10 because if you'll go to page 22?

11 A. Uh-huh.

12 Q. The second sentence on that page.
13 That phrase "doctors in the community." Not
14 community doctors, but "Doctors in the
15 community --

16 A. Uh-huh.

17 Q. -- are often unaware of the risks of
18 mesh."

19 You see that sentence?

20 A. I see that.

21 Q. Are you aware of any study that
22 supports that opinion? It's not referenced to
23 anything.

24 A. Well, I think we draw that from our

1 studies where we were in Oklahoma at a tertiary
2 care center, and we did a study where we saw 75
3 percent of patients who came to us with mesh
4 complications with the sling complications.

5 They -- when we asked them who
6 referred you to us, they said, you know, we -- I
7 came here based on the referral from a friend or
8 the church. And when we talked to the
9 physicians, they were like OB-GYNs, know this was
10 a problem. So it's actually documented in the
11 literature how -- how these mesh complications
12 may be seen, but most often they are told that
13 maybe just give the patient estrogen and it would
14 go away and it would end.

15 Q. Is estrogen an accepted form of
16 therapy for some mesh complications?

17 A. You know, to the -- this type of
18 mesh complications pertaining to TTVT-O and such
19 was something that I think crept up on the
20 community, and a lot of times neither the
21 community physicians nor us knew how to deal with
22 them.

23 I mean, they came about and we were
24 looking at ways to take care of the mesh problem,

1 take care of the sling erosion problem
2 nonsurgically. We did try estrogen and you may
3 find references in the literature that it was
4 advocated at one point, but it really fell out of
5 favor because it just didn't work.

6 Q. Okay. There was an FDA paper you
7 reference in your report issued in 2008.

8 A. Okay.

9 Q. Are you aware of that?

10 A. Yes.

11 Q. Did that FDA paper warn of the risks
12 associated with mesh implantation?

13 A. Okay.

14 Q. Did it?

15 A. So what's the question?

16 Q. My question is: Did the FDA 2008
17 paper address the issue of --

18 A. Yeah, that was the FDA warning,
19 warning of.

20 Q. -- risks of mesh?

21 A. They were -- they were alerting the
22 community of -- of complications associated with
23 the mesh and the sling that they were seeing.

24 Q. Okay. And did that go to doctors in

1 the community?

2 A. It was pretty much a media blast.

3 So whoever followed that probably learned about
4 it quickly.

5 Q. And so your statement,

6 "Unfortunately, doctors in the community are
7 often not aware of the risks of mesh" would
8 predate 2008?

9 MS. THOMPSON: Object to form.

10 THE WITNESS: Well, the study
11 that we did was after that time. So
12 doesn't seem like that filtrated into the
13 community.

14 BY MR. OTTAWAY:

15 Q. And did you try to in your study --
16 and please refer me to the study you're
17 referencing if it's in your materials there.

18 A. Sure.

19 Q. I'd like to know which study it is.

20 A. Uh-huh. It's the -- in the Oklahoma
21 Medical Journal. I don't know what year it was,
22 whether it's 2012 or '13. So...

23 Q. Okay. Did you make an effort in
24 that study to determine whether this statement

1 "Doctors in the community are not aware of the
2 risks of mesh" was post or pre-2008, the
3 implantation?

4 A. The study was done in 2012, '13,
5 whenever it was published. So, I mean, you can
6 draw a conclusion. If the warning came in 2008
7 and the study is published a few years later
8 whether the physicians really got the message or
9 not. I think that the -- you know, they -- they
10 didn't refer us the patients and it doesn't seem
11 like they were aware of the mesh problems that
12 was going on. Whether -- yeah, go ahead.

13 Q. No, go ahead. Finish your answer,
14 please.

15 A. So the study basically said about 75
16 percent of people were self-referred but not
17 referred by the surgeon who did their surgery.

18 Q. And it's from that study you
19 determined that "Doctors in the community are
20 often not aware of the risks of mesh"?

21 A. That's -- that's the -- that's what
22 we have observed.

23 Q. And did that study -- and again, you
24 know, I know the study you're referencing on that

1 you, Dr. Shobeiri.

2 A. Okay.

3 MR. OTTAWAY: And I guess let
4 me -- I'm not certainly going to stop you
5 from asking your questions, Margaret, but
6 let me say for purposes of the record,
7 since this is the first one of these we've
8 done, I'm not sure what the protocol is and
9 so I would object to the questioning. But
10 you are certainly free to ask it.

11 MS. THOMPSON: Okay. And I'll
12 tell you that we've never had any
13 restrictions on redirect questioning by --
14 by plaintiff's counsel. So, but your
15 objection is on the record.

16 BY MS. THOMPSON:

17 Q. Dr. Shobeiri, are all of the
18 opinions in your report supported by the
19 peer-reviewed medical literature?

20 A. Yes.

21 Q. And did you provide some examples of
22 that literature supporting your opinions in the
23 body of the report as footnotes?

24 A. Yes. Not everything, but some of

1 them.

2 Q. And there are other examples in the
3 84-page list of references as well?

4 A. Yes.

5 Q. So if you would go through the
6 report and look at Footnote 2.

7 And do those, some of the references
8 in Footnote 2, deal with the opinions that
9 Mr. Ottaway was asking you about earlier?

10 A. True.

11 Q. And how about Footnote 3?

12 A. True.

13 MR. OTTAWAY: Object to the form
14 of both those questions, but go ahead.

15 BY MS. THOMPSON:

16 Q. And --

17 MR. OTTAWAY: You may answer,
18 Doctor.

19 BY MS. THOMPSON:

20 Q. Are the opinions that Mr. Ottaway
21 asked you about earlier supported by Footnote 5?

22 MR. OTTAWAY: Same objection.

23 May I have a standing objection, counsel?

24 MS. THOMPSON: Uh-huh. You may.

1 MR. OTTAWAY: Thank you.

2 MS. THOMPSON: Because I'm going
3 to do several of them.

4 MR. OTTAWAY: I know you are. As
5 long as you give me a standing objection, I
6 won't make it.

7 BY MS. THOMPSON:

8 Q. Okay.

9 A. True.

10 Q. And Footnote 7?

11 A. Yes.

12 Q. Footnote 8?

13 A. Yes.

14 Q. Footnote 14?

15 A. Yes.

16 Q. Footnote 17?

17 A. Yes.

18 Q. Footnote 22?

19 A. Yes.

20 Q. Footnote 23?

21 A. Yes.

22 Q. Footnote 25?

23 A. Yes.

24 Q. And Footnote 26?

1 A. Yes.

2 Q. There were also some specific
3 questions regarding literature supporting
4 opinions that you gave here today, and I don't
5 have those articles with me, but these are all
6 contained on your reliance list.

7 And would you identify this article,
8 please?

9 A. Sure. This is the "Salvage Surgery
10 After Failed Treatment of Synthetic Mesh Sling
11 Complications" by Dr. Blaivas.

12 Q. And -- and it's published in what
13 journal?

14 A. It's -- let me see. This is not the
15 -- okay. There we are. Urology.

16 Q. And is that a peer-reviewed journal?

17 A. That's a peer-reviewed journal.

18 Q. Could you just read that last
19 sentence of that article?

20 A. Yeah. It goes to the point that I
21 made earlier that generally mesh sling
22 complications repair may require multiple
23 surgeries.

24 Q. And read the very last sentence of

1 the conclusions in the main report in the main
2 article.

3 A. This?

4 Q. This last sentence.

5 A. So basically what the authors
6 concluded was that the most difficult problem to
7 treat is pain, with only 28 percent of patients
8 with pain considering salvage operation is
9 success.

10 Q. So does that support your opinion
11 that -- that as many as 50 percent of patients
12 with pain do not get resolution after surgery to
13 remove it?

14 A. Yes.

15 MR. OTTAWAY: Objection to the
16 form of the question.

17 BY MS. THOMPSON:

18 Q. You also were asked some questions
19 about community doctors and their knowledge of
20 mesh complications?

21 A. Yes.

22 Q. And you cited an article that you
23 were one of the authors about Oklahoma.

24 And are there other articles

1 that address that same issue that you're aware
2 of?

3 A. Yes.

4 Q. For example, could you identify this
5 article that is also on your reliance list and
6 then read that highlighted?

7 A. Sure. So basically this is a
8 journal from the Female Pelvic Medicine
9 Reconstructive Surgery, which is the journal of
10 American Urogyne Society, and the authors -- this
11 is the one that we had quoted Hanson saying that
12 similar to other reports fewer than 50 -- fewer
13 than 25 percent of women were referred by the
14 surgeon that placed their mesh.

15 This may contribute to the continued
16 use of these products, as the physicians placing
17 them may not be fully aware of their own mesh
18 complications.

19 Q. And when was that article published?

20 A. That was I think in 2014 or '15.

21 Let me look. Ah, there we are. 2014.

22 Q. And could you identify this article,
23 when it was published, and what journal?

24 A. So let me just see. So the authors

1 here conclude that one of the things they say
2 that there's a management gap in the treatment
3 outcome related to management of mid-urethral
4 sling complications and this was in information
5 in health care. And let me see. It was a review
6 by Lee and Zimmer. And let me just see.

7 How do you move the screen in? I
8 need to look at the cite.

9 I need to look at that cite.

10 Q. It's in Expert Review of Medical
11 Devices.

12 A. Okay. Yeah. So the Expert Review
13 of Medical Devices in 2015.

14 Q. And could you read that highlighted
15 part of that?

16 A. If I can get to there. Was that the
17 one I just -- this one?

18 Q. Yeah.

19 A. Okay. So there's a knowledge gap in
20 treatment outcomes related to management of
21 mid-urethral sling complications.

22 MS. THOMPSON: All right. That's
23 all.

24 MS. FISCHER: Excuse me. Who is

1

FURTHER EXAMINATION

2

BY MS. THOMPSON:

3

4

5

Q. Dr. Shobeiri, did you consider and
critically assess literature that was both
favorable and unfavorable to your opinions?

6

A. Yes, I did.

7

MS. THOMPSON: That's it.

8

MR. OTTAWAY: You have the right
to read and sign this deposition,
Dr. Shobeiri, and you should consult with
Margaret and see what you wish to do.

12

MS. THOMPSON: You will.

13

THE WITNESS: Thank you.

14

THE VIDEOGRAPHER: The time now
is 2:19. This deposition has concluded.

16

(Signature having not been
waived, the taking of the deposition
concluded at 2:19 p.m.)

19

20

* * *

21

22

23

24